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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/692,090 | 10/23/2003 | Shigeru Nemoto | KITO2.001DV5 | 8325 |

20995 7590 02/27/2007
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| EXAMINER | |
|--------------------|--------------|
| DESANTO, MATTHEW F | |
| ART UNIT | PAPER NUMBER |
| 3763 | |

| SHORTENED STATUTORY PERIOD OF RESPONSE | NOTIFICATION DATE | DELIVERY MODE |
|--|-------------------|---------------|
| 3 MONTHS | 02/27/2007 | ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 02/27/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/692,090 | NEMOTO, SHIGERU | |
| | Examiner | Art Unit | |
| | Matthew F. DeSanto | 3763 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,9,10,12 and 13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,9,10,12 and 13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>5/19/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 3, 9, 10, 12, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Botich et al. (USPN 5,407,431), in view of Ericson et al. (US Pub 20010014996 A1) and Skakoon et al. (USPN 4,804,368).

Botich et al. discloses a pre-filled syringe (Col. 11, lines 14-24) with a syringe barrel comprising a flange that has a front and rear surface, wherein the front surface is roughened (Col. 11, lines 14-24, see figure 1) "to provide a greater coefficient of friction". The grooves (83) have a regular patterned of roughness since each groove is roughened and the roughness has a convex and concave pitch over the front surface of the flange because of the valleys and ridges that are formed by the grooves (83). Botich et al. fails to disclose "wherein the cross section of the roughened surface has a roughness of about No. 20 to 1500 as expressed in terms of count of sand paper" and "wherein at least one of the front and rear surface is randomly roughened".

Ericson et al. discloses a wedge clamp type termination for elevator tension members, but more importantly Ericson et al. teaches using sandblasting to raise the coefficient of friction of a surface (paragraph [0036]). Ericson et al. further teaches

other methods of increasing the surface friction, which include etching, machining, knurling and other suitable equivalents.

Skakoon et al. discloses an infusion apparatus with a cylinder holder that includes a flange insertion groove that allows all different types of syringes to fit into the cylinder holder (Column 5, line 15-35).

Therefore, at the time of the invention it would have been obvious to use sandblasting as another means of roughening the front surface of the flange to create a greater coefficient of friction between the fingers and thumb because it is well known that there are many methods that can be used to increase surface friction as taught by Ericson et al. By using this method of increasing the coefficient of friction, the cross section of the roughened surface having a roughness of about No. 20 to 1500 as expressed in terms of count of sand paper would be an obvious modification since the range lacks any criticality or special feature and thus such a range would have been obvious to one skilled in the art wishing for a particular roughness and friction.

The examiner would also like to note that by using sandblasting, it would cause random roughening because sand is being blasted into the object, thus causing the sand to be randomly placed into the object due to the force being exerted on the sand, thus creating a random pattern after each injection. This pattern can be controlled and follow a regular pattern if this method is used to form sections of roughened areas, thus creating a regular pattern from the roughened areas. Ericson et al. also teaches the formation of small ridges and valleys, which further supports the fact that the roughened section will have a convex and concave pitch (paragraph [0036]).

It would also be obvious to combine the teachings of Botich et al. and Ericson et al. with Skakoon et al., because Skakoon et al. discloses the benefit of using an automated infusion apparatus because the apparatus allows for a more precise and accurate way to infuse drugs and treatment into a patient (Column 2, line 48-55).

Response to Arguments

3. Applicant's arguments filed 11/22/06 have been fully considered but are moot in view of the new ground(s) of rejection.

4. With regards to the arguments of unexpected results, the examiner needs evidence as to the criticality of the unexpected results. According to the MPEP it would be obvious to combine the Biotech et al and Ericson et al. since it would only take routine experimentation to find the specific counts of sandpaper as expressed in the claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew F. DeSanto whose telephone number is 571-272-4957. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick LUCCHESI can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 3763

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Matthew DeSanto
Art Unit 3763
February 20, 2007

